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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,551	04/27/2006	Edward Fey	50047/015002	5268

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

CLARK, AMY LYNN

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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02/04/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/559,551	Applicant(s) FEY ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10-17 and 20-56 is/are pending in the application.
- 4a) Of the above claim(s) 10, 12-17 and 20-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2009 has been entered.

Acknowledgment is made of the receipt and entry of the amendment filed on 11/13/2009 with the cancellation of claims 3-9, and newly amended claims 1 and 11-13, 15-17.

Election/Restrictions

The election/restriction requirement remains for the reasons of record.

Claims 6-10, 12-17 and 20-56 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/17/2008.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1655

Any rejection found in the previous Office Action and not repeated herein has been withdrawn based upon Applicants' amendments to the claims, wherein Applicants now claim that the composition consists essentially of two or more ingredients.

Claims 1 and 11 are being examined on the merits.

Claim Objections

Claim 11 is objected to because of the following informalities: The term "oat straw (*Avena sativa*) SE" contains "SE", which appears to be an acronym or abbreviation but is missing the full name of "SE". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 1 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of claim 1 are rendered uncertain by the phrase "a joint enhancing composition adapted for oral administration, wherein the composition consists essentially of octacosanol (defatted wheat germ oil)...and, optionally, i) one or more substances selected from elecampane root (*Inula* sp.), L-cysteine, vitamin B1 (thiamin HC1), white oak bark (*Quercus alba*), *Aloe vera* gel, black cohosh (*Cimicifuga*

Art Unit: 1655

racemosa), androstenedione, shitake mushroom (*Lentius elodes*), and ii) one or more agents selected from the group consisting of an analgesic, an antibiotic, an antiviral, an anti-inflammatory, an anesthetic, an enzyme, and an immunosuppressive agent” because it is unclear what Applicant means by octacosanol (defatted wheat germ oil) and it is unclear if Applicant is claiming that the optional ingredients are included in the composition consisting essentially or if the optional ingredients are additional active ingredients added to the composition. With regards to “octacosanol (defatted wheat germ oil)” is Applicant claiming that octacosanol is found in defatted wheat germ oil, is defatted wheat germ oil or is derived from wheat germ oil? Further, it is unclear if Applicant is claiming that both the ingredients of i.) and ii.) are optional ingredients or if the optional ingredients are from i.). Please note that if Applicant is claiming i.) and/or ii.) as additional ingredients, that this would raise written description issues under 112 1st paragraph because the composition is a composition consisting essentially of, which means that no additional active ingredients can be added to the composition. The additional ingredients in i.) and ii.) are additional active ingredients. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of claim 11 are rendered uncertain by the phrase “consisting essentially of octacosanol (defatted wheat germ oil), oat straw (*Avena sativa*) SE, oat straw (*Avena sativa*) powder, bromelain, vitamin B5, L-methionine, quercetin...” because it is unclear if Applicant is claiming that the composition of claim 11 is this combination of ingredients only or if Applicant is claiming the combination of

Art Unit: 1655

ingredients in claim 1 and additionally the claims of claim 11. In claim 1, Applicant does not claim "oat straw (*Avena sativa*) SE", so it is unclear if Applicant means that the oat straw in claim 1 is "oat straw (*Avena sativa*) SE", or if Applicant is claiming this as an additional ingredient. Please note that if Applicant is claiming "oat straw (*Avena sativa*) SE" as an additional ingredient, that this would raise written description issues under 112 1st paragraph because the composition is a composition consisting essentially of, which means that no additional active ingredients can be added to the composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Please note that neither the specification nor the claims define the term "Oat straw SE". Therefore, the Examiner is interpreting "Oat straw (*Avena sativa*) SE" to be oat straw selenium (since selenium's abbreviation is Se) and interpreting that oat straw selenium means that oat straw contains selenium. Therefore, the rejection below is based upon this interpretation.

Claim Rejections - 35 USC § 103

Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima et al (Q, JP 04-278061 A, Translation of Abstract), in view of Reiners (O*, DE 10118999 A1, Translation provided in the previous office action), Morino et al. (P*, JP 09-176010 A, Translation provided in the previous office action), Maurer et al. (N*, EP 1208849 A1, Abstract provided previously),

Art Unit: 1655

<http://web.archive.org/web/20020616220742/http://godsremedy.com/hepatitis/what.htm>

(U* provided previously), Kast (V*, PubMed Abstract provided previously),

Holistic Online (W*,

[http://web.archive.org/web/20001029192423/http://holisticonline.com/Herbal-](http://web.archive.org/web/20001029192423/http://holisticonline.com/Herbal-Med/Herbs/h70.htm)

[Med/Herbs/h70.htm](http://web.archive.org/web/20001029192423/http://holisticonline.com/Herbal-Med/Herbs/h70.htm)) and Vitamin B5 (Pantothenic acid) (X*,

[http://web.archive.org/web/20030524163420/http://www.health-](http://web.archive.org/web/20030524163420/http://www.health-diets.net/healthsearch/b5_vit.htm)

[diets.net/healthsearch/b5_vit.htm](http://web.archive.org/web/20030524163420/http://www.health-diets.net/healthsearch/b5_vit.htm)).

Nakajima teaches obtain a nutritious food for recovery of fatigue and relief from stress of physiological activity (which reads on joint enhancer, since stress of physiological activity causes joint stress) containing octacosanol and an amino acid, wherein the amino acid can be methionine and wherein methionine is preferably contained at an amount of ≥ 10 pts.wt. based on 1 pts.wt. octacosanol.

Reiners teaches a composition effective against cell damage, which can lead to arthritis (which reads on joint enhancer, since it helps to prevent arthritis), comprising oat extract and L-methionine (See abstract) and further optionally comprising vitamin from the B-vitamin family (See translation).

Morino teaches a composition for treating rheumatoid arthritis (which reads on joint enhancer) comprising quercetin.

Maurer teaches bromelain is used for the manufacture of a medicament for treating rheumatoid arthritis.

Art Unit: 1655

<http://web.archive.org/web/20020616220742/http://godsremedy.com/hepatitis/what.htm> teaches that oat straw herb (which reads on oat straw and oat straw SE, since oat straw intrinsically contains Selenium) is useful for treating arthritis.

Kast teaches that borage oil has shown so benefit in the treatment of rheumatoid arthritis.

Holistic Online teaches that horsetail is a folk remedy for arthritis and that the Chinese also use it to treat arthritis.

Vitamin B5 (Pantothenic acid) teaches that vitamin B5 supplements treat rheumatoid arthritis.

it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition taught by Nakajima by combining oat straw (*Avena sativa*), L-methionine, vitamin B₅, horsetail, oat straw powder, quercetin, borage seed oil and bromelain, which are all ingredients that have the same functional effect of treating arthritis, as clearly taught by Nakajima, Reiners, Morino, Maurer, <http://web.archive.org/web/20020616220742/http://godsremedy.com/hepatitis/what.htm>, Kast, Holistic Online and Vitamin B5 (Panthothenic acid). Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed ingredients of oat straw (*Avena sativa*), L-methionine, vitamin B₅, horsetail, oat straw powder, quercetin, borage seed oil and bromelain for their known benefit in treating arthritis and, therefore, improving joints, since each claimed ingredient is well known in the art for the same purpose, as useful for treating arthritis and, therefore, improving joints, and for the following reason:

Art Unit: 1655

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach oat straw (*Avena sativa*), L-methionine, vitamin B₅, horsetail, oat straw powder, quercetin, borage oil and bromelain, are useful for treating arthritis and improving joints, it would have been obvious to combine these ingredients with the expectation that such a combination would be effective for treating arthritis and improving joints. Thus, combining them flows logically from their having been individually taught in prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art one would have been motivated to combine oat straw (*Avena sativa*), L-methionine, vitamin B₅, horsetail, oat straw powder, quercetin, borage oil and bromelain to provide a beneficial composition for the expected benefit of treating arthritis and improving joints because at the time the invention was made, the instantly claimed ingredients of oat straw (*Avena sativa*), L-methionine, vitamin B₅, horsetail, oat straw powder, quercetin, borage oil and bromelain were known to be useful for treating arthritis and improving joints, and since the ingredients and mode of administering the ingredients, which are one and the same as those claimed by Applicants, was known in

Art Unit: 1655

the art at the time the invention was made, as clearly taught by Nakajima, Reiners, Morino, Maurer,

<http://web.archive.org/web/20020616220742/http://godsremedy.com/hepatitis/what.htm>,

Kast, Holistic Online and Vitamin B5 (Panthothenic acid). Thus the combined composition of oat straw (*Avena sativa*), L-methionine, vitamin B₅, horsetail, oat straw powder, quercetin, borage oil and bromelain would have been expected to be even more effective for treating arthritis and improving joints because the claimed ingredients were all useful for this purpose, as clearly taught by Nakajima, Reiners, Morino, Maurer, <http://web.archive.org/web/20020616220742/http://godsremedy.com/hepatitis/what.htm>, Kast, Holistic Online and Vitamin B5 (Panthothenic acid).

Finally, one of ordinary skill in the art would have had a reasonable expectation of success to combine the following ingredients for treating arthritis and improving joints to gain the benefits of individual components as part of a composition for treating arthritis and improving joints: oat straw (*Avena sativa*), D-L-methionine, vitamin B₅, horsetail, oat straw powder, quercetin, borage seed oil and bromelain, to provide a beneficial composition for the expected benefit of treating arthritis and improving joints because at the time the invention was made, these ingredients were well known treating arthritis and improving joints, as clearly taught by Nakajima, Reiners, Morino, Maurer, <http://web.archive.org/web/20020616220742/http://godsremedy.com/hepatitis/what.htm>, Kast, Holistic Online and Vitamin B5 (Panthothenic acid).

Moreover, it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose the form that oat straw is in and to pick oat

Art Unit: 1655

straw powder because at the time the invention was made, it was known in the art that oat straw is useful for joint enhancement and can be used in joint enhancing compositions. Further, it was known to be obvious to modify the form of a plant for easier administration. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to claims 1 and 11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/
Examiner, Art Unit 1655